REMARKS

Applicant notes with appreciation that all previous rejections and objections have been withdrawn. One new basis for rejection has bee introduced. The following sections will discuss, in this order, 1) Amendments to the Claims; and 2) Rejection under 35 USC § 102.

1) Amendments to the Claims

a) Amendment to correct Listing of Claims filed September 9, 2003.

In the Amendment and Response filed on September 9, 2003, in conjunction with this Request for Continued Examination, Applicant submitted a Listing of Claims comprising amendments incorporating language agreed upon in a telephonic interview with the Examiner on August 12, 2003. These amendments comprised replacing the term "multivalent vaccine composition" with the term "multivalent composition for active idiotype immunotherapy," and amendment to indicate that the recited B-cells are from a "quasi-clonal" B-cell lymphoma. An interview summary was provided in the same Amendment and Response. However, in the claims presented in the Listing of Claims filed on September 9th, 2003, Applicant inadvertently omitted amendments entered in an Amendment and Response of December 12, 2001. Thus, the markings on the September 9, 2003 amended claims were inaccurate in that they indicated only the new amendments and did not indicated where the earlier-made amendments had been unintentionally omitted.

A new listing of claims is presented hereinabove, wherein the claims as listed on September 9, 2003 are amended to incorporate the amendments previously presented in the papers of December 12, 2001.

b) Additional Claim Amendments:

Claims 1 and 3 are additionally amended for reasons not related to patentability or in response to any rejection, but to clarify that the compositions of those claims comprise recombinant proteins (*e.g.*, recombinant proteins comprising variable regions of immunoglobulin molecules), but that the immunoglobulin molecules from which the recombinant proteins are derived (*i.e.*, via the nucleic acid encoding the immunoglobulin) need not themselves be recombinant. Support for the term "recombinant protein" is found, *e.g.*, in the Field of the Invention, on page 1 at line 7, in the Description of the Invention at page 24, line 3, and in the Example section, *e.g.*, at page 104, line 21. Claim 1 is also amended to clarify that the recited variable regions are derived from nucleic acid encoding the recited immunoglobulin molecules. Support for, and description of methods of deriving variable regions from nucleic acid encoding immunoglobulins is provided, *e.g.*, in Example 10, starting at page 88. Claim 31 is amended to

be consistent with the language of Claims 1 and 3.

Claim 30 is amended for reasons not related to patentability or in response to any rejection, but to indicate that the recited B-cell lymphoma cells are " from a patient." This language is found in previously presented Claims 28 and 29 [see, *e.g.*, Claim 29 at part i) of part a)]. Further support for this term is found throughout the specification, *e.g.*, in Example 10, at page 94, lines 9-10, which states: "Primers suitable for isolating variable regions from a patient's tumor are provided . . . "

All language included in these amendments is supported in the specification and does not constitute new matter.

Applicant notes that these amendments do not affect or alter the Remarks included in the Amendment and Response filed on September 9, 2003.

2) Rejection under 35 USC § 102

Claims 1, 3-6, and 25-32 are pending in the present case. The Examiner has rejected these Claims in an Office Action mailed October 21, 2003. Claims 1, 3-6, and 25-32 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Chen TT et al. (J. Immunology 1994; 153:4775-4787) (hereinafter "Chen").

The Claims Are Not Anticipated

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP 2131, citing *Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d. 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)*. The Examiner alleges that each of the limitations within Claims 1, 3-6, and 25-32 are anticipated by Chen. Office Action, pg. 2. Applicant respectfully disagrees.

As indicated by the Examiner, a particular immunoglobulin molecule may comprise a plurality of idiotopes. However, a single immunoglobulin molecule comprises *a single set* of idiotopes. Thus, different variable regions (*i.e.*, a single V_H and a single V_L) from within a single immunoglobulin molecule cannot be "from immunoglobulin molecules that differ by at least one idiotope."

The compositions recited in independent Claims 1, 25, 28, 30, and the claims dependent therefrom, specify that the compositions comprise *at least two recombinant protein molecules comprising variable regions of at least two immunoglobulin molecules*, and that these at least

two immunoglobulin molecules *differ by at least one idiotope*. Thus, the variable regions recited in the present claims are from at least two distinct immunoglobulins, and are not merely different variable regions (*i.e.*, V_H and V_L) of a single immunoglobulin.

The composition of Chen does not have all of the elements of the present claims, as discussed above. As indicated by the Examiner, Chen teaches a composition comprising an antibody (a "tumor idiotypic determinant," or "Id;" see, *e.g.*, Figure 1, p 4777) conjugated to a cytokine. The Examiner asserts that the antibody is a multivalent compound because each arm of the antibody has its own valency, and that each variable region of the antibody can potentially have more than one idiotope. However, the composition of Chen comprises a single antibody, the 38C13 Id. See, *e.g.*, 4776, first sentence of column 1: ". . . we have shown that a fusion between *the* 38C13 tumor Id and GM CSF converts *the* tumor Id into a strong immunogen . . " (*emphasis added*). Chen further makes clear that the antibody-cytokine fusion disclosed consists of heavy and light chain variable regions from a single immunoglobulin, the 38C13 Id, stating that "the resulting [chimeric Id] protein is composed of *the* 38C13 heavy chain variable region (V_H38C) and *the* light chain variable region (Vκ38C) fused to the human IgG1 heavy chain constant region (Cγ1) and κ light chain constant region (Cκ), respectively" (Chen, p4777, column 1, emphasis added). Chen therefore teaches only recombinant variable regions from a single antibody. For the reasons recited above, the single antibody of Chen cannot by itself provide the recited "at least two recombinant proteins comprising variable regions of at least two immunoglobulin molecules" wherein the "at least two immunoglobulin molecules differ by at least one idiotope." As such, the composition of Chen does not teach each and every element as set forth in Claims 1, 25, 28, 30, and the claims dependent therefrom, and thus does not anticipate these claims under 35 U.S.C. § 102(b). Applicant respectfully requests that this rejection be removed.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that all reasons for rejection should be removed and Applicant's claims should be passed to allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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